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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,655

09/23/2003

Nyle S. Elliott

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EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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10/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,655

Applicant(s)

ELLIOTT, NYLE S.

Examiner

Adam Marcetich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 21 and 23 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Agreement was reached in an interview 09 August 2007 to withdraw finality of a rejection under 35 USC § 103(a) over Brady to claim 1. See interview summary dated 16 August 2007.
2. Rejection of claim 23 under 35 USC § 112 and objection to claim 1 have been withdrawn in view of amendments to the claims filed 09 August 2007.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-5, 7-12, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al. (US Patent 6,171,289) in view of Brady (US Patent 6,723,040).
5. Regarding claim 1, Millot discloses an alert device for detecting the presence of fecal matter comprising:
 - a pad having an aperture (column 3, lines 23-25 and Figs. 1 and 2, ostomy seal 5 having through passage 8);
 - an alarm attached to said pad (column 3, lines 60-65 and Fig. 2, electronic circuit 19);

a first and second conductor extending from said aperture to said alarm (column 3, lines 39-45 and Fig. 2, printed circuit tracks 15 and 16);

Millot discloses the invention as substantially claimed. See above. However, Millot lacks a plug with a third and forth conductor on said plug as claimed [claim 1]. Brady discloses a plug with a third and forth conductor on said plug, said plug removably secured to said pad at said aperture (column 4, lines 10-18 and 53-54; Fig. 1, tubular body 18 having sensors 40 and 42). Sensors 40 and 42 of Brady are substantially ring-shaped. Brady provides the advantage of alerting a patient to the presence of fecal matter in the colon and temporarily blocking discharge (column 2, lines 26-29 and 35-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot as discussed with the plug and third and forth conductors as taught by Brady in order to alert a patient and temporarily block discharge.

6. Regarding claims 2-5, Millot discloses an alarm emitting audible, visible or tactile alarms, or transmitting a signal to a remote location (column 3, lines 60-65).

7. Regarding claim 7, Millot discloses an alert device wherein said pad is a flexible, elastomeric material (column 2, lines 26-46 especially lines 26-29 and 37-38, "flexible support").

8. Regarding claim 8, Millot discloses the invention as substantially claimed. See above. However, Millot lacks an inflatable cuff encircling said plug. Brady discloses an inflatable cuff encircling said plug (column 5, lines 13-16 and Fig. 1, cuff or bladder 60). Brady provides the advantage of forming a seal between a patient and blocking device

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for a more secure seal. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot as discussed with the inflatable cuff as taught by Brady in order to form a more secure seal.

9. Regarding claim 10, Millot discloses the invention as substantially claimed. See above. However, Millot lacks an absorbent sleeve disposed about said tube. Brady discloses an absorbent sleeve disposed about said tube (column 6, lines 23-29, seal 190 made of medical grade cosmetic foam). Brady provides the advantage of absorbing any leakage bypassing a seal between the patient and tubular body 18 (column 6, lines 28-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot with the absorbent sleeve as taught by Brady in order to absorb any leakage bypassing a patient seal.

10. Regarding claim 11, Millot discloses the invention as substantially claimed. See above. However, Millot lacks a filter. Brady discloses a filter (column 4, lines 43-47 and filter 28). Brady provides the advantage of reducing odors. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot as discussed with the filter as taught by Brady in order to reduce odors.

11. Regarding claim 12, Millot discloses an adhesive ring attached to one side of the pad (column 3, lines 27-33 and Fig. 3, adhesive composition 11).

12. Regarding claims 9 and 21, Millot discloses the invention as substantially claimed. See above. However, Millot lacks third and fourth conductors each comprising

a lower ring and an upper ring as claimed [claim 21]. Brady discloses third and fourth conductors comprising:

- a lower ring (column 4, lines 58-62 and Fig. 1, sensor 42);
- an upper ring (column 4, lines 58-62 and Fig. 1, sensor 40); and
- an upwardly extending section extending between the upper and lower rings (column 4, lines 58-62 and Fig. 1, conductor 44).

Brady provides the advantage of alerting a patient to the presence of fecal matter in the colon and temporarily blocking discharge (column 2, lines 26-29 and 35-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot as discussed with the lower and upper rings as taught by Brady in order to alert a patient and temporarily block discharge.

Brady discloses third and fourth conductors in the form of sensors 40 and 42. With respect to the claimed duplication of rings and upwardly extending sections, the MPEP 2144.04(VI)(B) requires an invention made through duplication of parts to have a "new" and "unexpected" result for patentability. The claimed invention lacks these qualities. It is well known in the art that providing additional electrical contacts provides redundancy to ensure connection if one electrode fails. Therefore, the duplication of rings and upwardly extending sections does not provide a "new" and "unexpected" result.

13. Regarding claim 23, Millot depicts an alert device wherein the first and second conductor each comprise a first section extending from a circuit board to the aperture

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and a ring extending around the aperture (Fig. 2, printed circuit tracks 15 and 16 extending from electronic circuit 19 and substantially forming a ring). Examiner interprets the language "ring extending around the aperture," broadly to include the circular shape of printed circuit tracks 15 and 16 extending past electrodes 17 and 18 as depicted in Fig. 2. See online dictionary entry for "ring."

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Millot et al. (US Patent 6,171,289) in view of Brady (US Patent 6,723,040) in view of McDonnell (US Patent 4,121,589).

15. Regarding claim 6, Millot in view of Brady discloses the invention as substantially claimed. See above. However, Millot in view of Brady lacks mating threads securing a plug to an aperture. McDonnell discloses threads for the purpose of securely engaging an ostomy appliance to a patient (column 4, lines 4-7 and Fig. 1, element 7). The pad of Millot and plug of Brady are adaptable to interface with the threading of McDonnell. The pad of Millot is adapted to fit around the plug of Brady as discussed for claim 1 above, and is therefore also adaptable to interface with the threading of McDonnell. McDonnell provides the advantage of a secure attachment and avoiding leakage. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Millot in view of Brady as discussed with the threading as taught by McDonnell in order to securely attach a plug to a pad.

Response to Arguments

16. Applicant's arguments filed 09 August 2007 with respect to claims 1-5, 7-11 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

17. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A search for incontinent alert devices having a tubular structure with a ring-shaped sensor revealed prior art, which has been made of record. However, no instance of prior art discloses a ring electrode present on an inner surface of a tubular structure.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761



AMM

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

